DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

October 10, 2014

Bio-Detek, Inc.
Shannon Duhamel
Regulatory Affairs Specialist
269 Mill Road
Chelmsford, Massachusetts 01824-4105

Re: K133441
Trade/Device Name: OneStep CPR II Adult Multi-Function Electrode
Regulation Number: 21 CFR 870.5310
Regulation Name: Automated External Defibrillator
Regulatory Class: Class III
Product Code: MKJ
Dated: August 28, 2014
Received: August 29, 2014

Dear Shannon Duhamel,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kenneth J. Cavanaugh -S

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) number (if known): K133441

Device Name: OneStep CPR II Adult Multi-Function Electrode

Intended Use:

- Defibrillation
- Cardioversion
- Noninvasive Pacing
- ECG Monitoring
- CPR Sensor

For use on adult patients with **ZOLL**® R Series® defibrillator by trained personnel only, including:

- Physicians
- Nurses
- Paramedics
- Emergency Medical Technicians
- Cardiovascular Laboratory Technicians

The OneStep CPR II Adult Electrodes are not indicated for use on a patient less than 8 years of age or weighing less than 55 lbs (25kg).

Prescription Use __X__ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use ____ (21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

K133441

BIO-DETEK
INCORPORATED

510(k) Summary:

Submitter's Name and Address:
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A Subsidiary of **ZOLL**® Medical Corporation
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Contact Person:
Shannon Duhamel
Regulatory Affairs Specialist
Tel. (978) 421-9574
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Date Summary Prepared:
October 10, 2014

Device Name / Proprietary Name:
ZOLL OneStep CPR II Adult Multi-Function Electrode (MFE)

RegulationCommon Name:
Automated External Defibrillator Multi-Function Electrodes

Classification Name:
Multi-Function Electrode, with CPR Aid
Accessory to an Automated External Defibrillator

Substantial Equivalence:
The **ZOLL OneStep CPR II** Multi-Function Electrode (MFE) is substantially equivalent to the predicate **ZOLL OneStep CPR** MFE that was FDA cleared per K110742 on 04/13/2011. The proposed electrode introduces the addition of a second sensor on the posterior pad which allows users to obtain accurate compression depth feedback while performing CPR on soft/ compressible surfaces. As with the predicate device, the **OneStep CPR II** MFE is intended for use with the **ZOLL R Series** Defibrillator. Both the predicate and the proposed **OneStep CPR II** Electrodes are presently in FDA Regulatory Class III category.

Description of Device:
As with the cleared predicate device (K110742), the **OneStep CPR II** MFE is intended for use with **ZOLL R Series** defibrillators for ECG Monitoring, Defibrillation, External

Noninvasive Pacing, Cardioversion and CPR Feedback for adult patients in either the hospital or pre-hospital environment. The currently marketed **OneStep CPR** MFE provides users with accurate depth compression feedback when CPR is performed on a firm surface – a known recommended practice. A recent publication[1] by the AHA acknowledges that "accelerometers are insensitive to mattress compression" and stresses the need for "continued development of optimal and widely available CPR monitoring".

The proposed device incorporates a second motion sensor on the posterior electrode which will allow rescuers to obtain accurate depth compression feedback when CPR is performed on soft/ compressible surfaces. The dual sensor technology works by detecting motion in the posterior sensor and communicating it to the anterior sensor to allow for compensation for a compressible surface underneath the patient. The accelerometers in each CPR sensor work in series to provide a signal to the defibrillator which interprets that signal to determine actual chest compression depth when compressions are performed on a compressible surface. The dual sensor technology can also be used on a solid surface as the design of the posterior sensor is not influenced by lack of movement.

As with the predicate device, the proposed electrode and wire harness with a ZOLL proprietary connector will have a pre-connect feature that enhances the user's ability to deliver immediate therapy. And like the predicate device, the **OneStep CPR II** electrode will also have the ability to perform a defibrillation self test and expiration date identification with the **ZOLL R Series** Defibrillator. Each electrode pad is structurally comprised of a solid hydrogel with a pure tin electrical conductive element having a polyethylene terephtalate (PET) backing with an adhesive perimeter suitable for coupling to patient skin during rescue and/or treatment.

Device Name: OneStep CPR II Adult Multi-Function Electrode

Intended Use:

- Defibrillation
- Cardioversion
- Noninvasive Pacing
- ECG Monitoring
- CPR Sensor

For use with **ZOLL**® R Series® defibrillator by trained personnel only, including:

- Physicians
- Nurses
- Paramedics
- Emergency Medical Technicians

[1] Meaney, P. A., et al. CPR Quality: Improving Cardiac Resuscitation Outcomes Both Inside and Outside the Hospital: A Consensus Statement From the American Heart Association. *Circulation* by AHA. 2013: 5.

- Cardiovascular Laboratory Technicians

The OneStep CPR II Adult Electrodes are not indicated for use on a patient less than 8 years of age or weighing less than 55 lbs (25kg).

Comparison of Technological Characteristics:
The intended use of the **OneStep Multi-Function** Electrodes as described in the Indications For Use and labeling has not changed as a result of this submission. The **OneStep CPR II** MFE that is the subject of this submission as compared to the ZOLL OneStep predicate electrode cleared in submission K110742 uses the same conductive materials, acrylic adhesive closed cell foam, and has a conductive area of the same dimensional size.

Testing:
The **OneStep CPR II** Electrode has been subjected to extensive performance testing to ensure the device meets all of its functional requirements and performance specifications as defined in applicable National/International recognized standards. Performance testing is provided in Section 18 of this submission.

The proprietary name is **ZOLL OneStep CPR II** Adult MFE which was formerly identified as OneStep Adult Dual Sensor. Testing and performance evaluations demonstrate that the safety and effectiveness of the **OneStep CPR II** Adult MFE is substantially equivalent to the predicate device.